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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,721	12/30/1999	MATTHEW S. REIMINK	1416.04US01	6766

7590

08/14/2002

Peter S. Dardi
Patterson, Thunte, Skaar & Christensen, P.A.
4800 IDS Center
80 South 8th Street
MINNEAPOLIS, MN 55402-2100

EXAMINER

HON, SOW FUN

ART UNIT

PAPER NUMBER

1772

DATE MAILED: 08/14/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/475,721

Applicant(s)

REIMINK ET AL.

Examiner

Sow-Fun Hon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-20 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-20, 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/13/02 has been entered.

Response to Amendment

Withdrawn Rejections

2. The 35 U.S.C. 112, 2nd paragraph rejection in Paper #6, paragraph 7 (mailed 09/13/01) of claims 1-3, 5-9 has been withdrawn due to Applicant's amendment in Paper # 13 (filed 05/13/02).

3. The 35 U.S.C. 102(b) rejection in Paper #6, paragraph 9 (mailed 09/13/01) of claims 1-3, 5-9 as being anticipated by Pietsch et al. has been withdrawn due to Applicant's amendment in Paper # 13 (filed 05/13/02).

Rejections Repeated

4. The 35 U.S.C. 102(b) rejection of claims 10-17 as being anticipated by Pietsch et al. has been repeated for the same reasons previously of record in Paper #6, paragraph 9 (mailed 09/13/01).

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5. The 35 U.S.C. 103(a) rejection of claims 18-19 over Pietsch et al. has been repeated for the same reasons previously of record in Paper #6, paragraph 11 (mailed 09/13/01).

6. The 35 U.S.C. 103(a) rejection of claim 20 over Pietsch et al. in view of Sumimoto Electric Co. for the same reasons previously of record in Paper #6, paragraph 12 (mailed 09/13/01).

New Rejections

Claim Rejections - 35 USC § 102

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1-2, 5, 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Cromie (US 3,722,004).

Cromie teaches struts made of metal (titanium) coated with carbon, which hold a disc for an occluder disc type heart valve, and an inorganic substrate (ring) of hard, wear-resistant metal (titanium) embedded in a plastic matrix with the outer circumference of the ring protruding from the plastic (abstract, column 1, lines 45-68). The plastic matrix is made of polycarbonate (column 2, lines 1-10) which is a rigid polymer.

Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 3, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cromie in view of Reul et al. (US 4,263,680).

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Cromie was discussed above and teaches a heart valve with an inorganic substrate partially covered with polymer, failing to teach a crosslinked polymer, and that the inorganic substrate material comprised metal, failing to teach ceramic.

Reul et al. teaches a heart valve with a substrate (ring) consisting of metal which is covered (coated) with crosslinked polymer (epoxy). Reul et al. teaches that ceramic can be used instead of metal (column 4, lines 20-55).

Because Reul et al. teaches that ceramic is a suitable alternative to metal for use as a heart valve substrate material, it would have been obvious to one of ordinary skill in the art to have used ceramic in place of the metal, and crosslinked polymer as the polymer in the invention of Cromie in order to obtain an alternate heart valve with the desired alternate physical properties.

11. Claims 6-7, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cromie in view of MacGregor (US 4,627,836).

Cromie was discussed above and teaches a heart valve with an inorganic substrate partially covered with polymer.

MacGregor teaches a heart valve made from a combination of rigid polymeric material, metal or ceramic material and carbon. The metal substrate is given as an example (column 3, lines 20-30 and column 4, lines 30-50). The thickness of the rigid porous rigid plastic coating is taught to be about 20 to 300 microns and the composite has a fatigue endurance limit (10⁷ cycles) of greater than 3000 psi shear strength. The polymer may be attached by flowing into the metal substrate thus forming a barb or anchor (column 5, lines 5-50).

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Because MacGregor teaches that the composite has a fatigue endurance limit (107 cycles) of greater than 3000 psi shear strength, it would have been obvious to one of ordinary skill in the art to have used the composite of MacGregor in the invention of Cromie in order to obtain a heart valve with the desired fatigue endurance limit.

Response to Arguments

12. Applicant's arguments with respect to claims 1-9 as being anticipated by Pietsch et al. have been considered but are moot in view of the new ground(s) of rejection.

13. Applicant's arguments with respect to claims 10-20 over Pietsch et al. as the primary reference have been fully considered but they are not persuasive.

a. Applicant argues that with respect to independent claim 10, the degree of flexibility is specifically recited with respect to bending, and that the support ring of Pietsch et al. cannot be bent by 100 degrees while remaining elastic.

Applicant is respectfully reminded that the cusps of the heart valve are taught to be flexible, not the support ring, and that crosslinked silicone rubber (polydimethylsiloxane) is taught to be particularly suitable for the flexible cusps, having high fatigue strength in alternate bending as well as a high breaking strength at a low Shore A hardness of 25-35, and an elongation at break of more than 400 % ('461, column 3, lines 15-20, column 4, lines 20-68 and column 5, lines 1-15). Because the crosslinked dimethylsiloxane has high fatigue strength in alternate bending as well as high breaking strength at a low Shore A hardness of 25-35, and an elongation at break of more than 400 %, it is the examiner's position that the composite can be bent by at least 100 degrees while remaining elastic, by about 180 degrees without extending the

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component beyond its elastic limit and by about 60 degrees for about 40 million cycles to about 400 million cycles without significant structural failure.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (703)308-3265. The examiner can normally be reached Monday to Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (703)308-4251. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0661.

SH
08/07/02


HAROLD PYON
SUPERVISORY PATENT EXAMINER
8/8/02